

CLAIMS

We Claim:

1. A method for treating a condition with a drug indicated for treatment of said condition, the method comprising the step of orally administering a dosage form containing said drug in a pharmaceutically acceptable carrier wherein said dosage form releases said drug from said dosage form at an ascending release rate for an extended time period.

10 2. The method described in claim 1 wherein said dosage form is an osmotic dosage form comprising:

- (a) a longitudinally compressed tablet core containing a plurality of layers wherein drug is contained in at least one layer and at least one other layer comprises a suitable fluid-expandable polymer;
- 15 (b) a semipermeable wall surrounding said longitudinally compressed tablet core to thereby form a compartment having an osmotic gradient to drive fluid from an external fluid environment contacting said semipermeable wall into said compartment; and
- (c) an orifice formed through said semipermeable wall and into said longitudinally compressed tablet core to permit drug to be released from within said compartment into said external fluid environment.

20 3. The method described in claim 2 wherein said longitudinally compressed tablet core comprises two layers and said drug is contained within a first layer and said fluid-expandable polymer is contained within a second layer and further wherein said orifice is formed through said semipermeable wall at a location adjacent to said first layer.

25 4. The method described in claim 3 wherein said osmotic dosage form additionally comprises an immediate-release dose of a drug applied as a coating onto the outer surface of said osmotic dosage form.

5. The method described in claim 2 wherein said longitudinally compressed tablet core comprises three layers and a portion of said drug is contained within a first layer and the remaining portion of said drug is  
5 contained within a second layer, wherein the concentration of drug contained within said first layer is less than the concentration of drug contained within said second layer, and wherein said fluid-expandable polymer is contained within a third layer and said orifice is formed through said semipermeable wall at a location adjacent to said first layer.

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6. The method described in claim 5 wherein said osmotic dosage form additionally comprises an immediate-release dose of a drug applied as a coating onto the outer surface of said osmotic dosage form.

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7. A method for treating ADHD, the method comprising the step of orally administering a dosage form containing a CNS-acting drug in a pharmaceutically acceptable carrier wherein said dosage form releases said CNS-acting drug from said dosage form at an ascending release rate for an extended time period.

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8. The method described in claim 7 wherein said CNS-acting drug is a CNS-stimulant drug selected from the group consisting of methylphenidate, d-threo-methylphenidate, amphetamine, dextroamphetamine, methamphetamine, phenylisopropylamine and pemoline.

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9. The method described in claim 8 wherein said CNS-stimulant drug is methylphenidate.

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10. The method described in claim 9 wherein said dosage form is an osmotic dosage form comprising:

6 (a) a longitudinally compressed tablet core containing a plurality of layers wherein methylphenidate is contained in at least one layer and at least one other layer comprises a suitable fluid-expandable polymer;

5 (b) a semipermeable wall surrounding said longitudinally compressed tablet core to thereby form a compartment having an osmotic gradient to drive fluid from an external fluid environment contacting said semipermeable wall into said compartment; and

10 (c) an orifice formed through said semipermeable wall and into said longitudinally compressed tablet core to permit methylphenidate to be released from within said compartment into said external fluid environment.

15 11. The method described in claim 10 wherein said longitudinally compressed tablet core comprises two layers and said methylphenidate is contained within a first layer and said fluid-expandable polymer is contained within a second layer and further wherein said orifice is formed through said semipermeable wall at a location adjacent to said first layer.

20 12. The method described in claim 11 wherein said osmotic dosage form additionally comprises an immediate-release dose of methylphenidate applied as a coating onto the outer surface of said osmotic dosage form.

25 13. The method described in claim 10 wherein said longitudinally compressed tablet core comprises three layers and a portion of said methylphenidate is contained within a first layer and the remaining portion of said methylphenidate is contained within a second layer, wherein the concentration of methylphenidate contained within said first layer is less than the concentration of methylphenidate contained within said second layer, and  
30 wherein said fluid-expandable polymer is contained within a third layer and said orifice is formed through said semipermeable wall at a location adjacent to said first layer.

14. The method described in claim 13 wherein said osmotic dosage form additionally comprises an immediate-release dose of methylphenidate applied as a coating onto the outer surface of said osmotic dosage form.

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15. A method for effectively treating ADHD for a prolonged therapy period of at least about 10 hours comprising administering methylphenidate in a dosage form that provides release of methylphenidate at an ascending release rate over an extended time period.

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16. A method for providing plasma methylphenidate concentrations that are substantially smoothly ascending over an extended time period comprising administering methylphenidate in a dosage form that provides release of methylphenidate at an ascending release rate over an extended time period.

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17. A dosage form comprising a drug in a pharmaceutically acceptable carrier wherein, following oral administration, said dosage form releases said drug from said dosage form at an ascending release rate for an extended time period.

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18. The dosage form described in claim 17 wherein said dosage form is an osmotic dosage form comprising:

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(a) a longitudinally compressed tablet core containing a plurality of layers wherein said drug is contained in at least one layer and at least one other layer comprises a suitable fluid-expandable polymer;

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(b) a semipermeable wall surrounding said longitudinally compressed tablet core to thereby form a compartment having an osmotic gradient to drive fluid from an external fluid environment contacting said semipermeable wall into said compartment; and

5 (c) an orifice formed through said semipermeable wall and into said longitudinally compressed tablet core to permit drug to be released from within said compartment into said external fluid environment.

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19. The dosage form described in claim 18 wherein said longitudinally compressed tablet core comprises two layers and said drug is contained within a first layer and said fluid-expandable polymer is contained within a second layer and further wherein said orifice is formed through said semipermeable wall at a location adjacent to said first layer.

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20. The dosage form described in claim 19 wherein said osmotic dosage form additionally comprises an immediate-release dose of a drug applied as a coating onto the outer surface of said osmotic dosage form.

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21. The dosage form described in claim 18 wherein said longitudinally compressed tablet core comprises three layers and a portion of said drug is contained within a first layer and the remaining portion of said drug is contained within a second layer, wherein the concentration of drug contained within said first layer is less than the concentration of drug contained within said second layer, and wherein said fluid-expandable polymer is contained within a third layer and said orifice is formed through said semipermeable wall at a location adjacent to said first layer.

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22. The dosage form described in claim 21 wherein said osmotic dosage form additionally comprises an immediate-release dose of a drug applied as a coating onto the outer surface of said osmotic dosage form.

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23. A dosage form containing a CNS-acting drug in a pharmaceutically acceptable carrier wherein said dosage form, following oral administration, releases said CNS-acting drug from said dosage form at an ascending release rate for an extended time period.

24. The dosage form described in claim 23 wherein said CNS-acting drug is a CNS-stimulant drug selected from the group consisting of methylphenidate, d-threo-methylphenidate, amphetamine,  
5 dextroamphetamine, methamphetamine, phenylisopropylamine and pemoline.

25. The dosage form described in claim 24 wherein said CNS-stimulant drug is methylphenidate.

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26. The dosage form described in claim 25 wherein said dosage form is an osmotic dosage form comprising:

15 (a) a longitudinally compressed tablet core containing a plurality of layers wherein methylphenidate is contained in at least one layer and at least one other layer comprises a suitable fluid-expandable polymer;

20 (b) a semipermeable wall surrounding said longitudinally compressed tablet core to thereby form a compartment having an osmotic gradient to drive fluid from an external fluid environment contacting said semipermeable wall into said compartment; and

25 (c) an orifice formed through said semipermeable wall and into said longitudinally compressed tablet core to permit methylphenidate to be released from within said compartment into said external fluid environment.

27. The dosage form described in claim 26 wherein said longitudinally compressed tablet core comprises two layers and said methylphenidate is contained within a first layer and said fluid-expandable polymer is contained within a second layer and further wherein said orifice is formed through said semipermeable wall at a location adjacent to said first layer.

28. The dosage form described in claim 27 wherein said osmotic dosage form additionally comprises an immediate-release dose of methylphenidate applied as a coating onto the outer surface of said osmotic dosage form.

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29. The dosage form described in claim 26 wherein said longitudinally compressed tablet core comprises three layers and a portion of said methylphenidate is contained within a first layer and the remaining portion of said methylphenidate is contained within a second layer, wherein  
10 the concentration of methylphenidate contained within said first layer is less than the concentration of methylphenidate contained within said second layer, and wherein said fluid-expandable polymer is contained within a third layer and said orifice is formed through said semipermeable wall at a location adjacent to said first layer.

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30. The dosage form described in claim 29 wherein said osmotic dosage form additionally comprises an immediate-release dose of methylphenidate applied as a coating onto the outer surface of said osmotic dosage form.

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31. The dosage form described in claim 30 wherein said coating comprises an antidegradation agent.

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32. The dosage form described in claim 31 wherein said antidegradation agent is phosphoric acid.

33. The dosage form described in claim 29 wherein said semipermeable membrane comprises cellulose acetate and a flux-enhancing agent.

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34. The dosage form described in claim 33 wherein said flux-enhancing agent is a copolymer of ethylene and propylene oxide.